REMARKS

This is a Response to the Official Action dated October 20, 2004. A Notice of Appeal and a petition for a three-month extension of time through April 20, 2005, with the appropriate fee, accompany this Response.

After amendment of the claims as indicated above, claims 1, 47, 50, 51 and 55 will remain pending in this application. Claim 49 has been canceled, without prejudice, and its subject matter has been incorporated into independent claim 1.

Claim 1 has been amended to further define the structure of the targeted therapeutic delivery system such that the lipid of the stabilized lipid microspheres comprises at least one phosphatidylcholine, at least one phosphatidylethanolamine, and at least one phosphatidic acid. Support for such an amendment can be found throughout the specification, for example, at page 33, lines 1-6.

In view of the foregoing amendment, as well as the arguments that follow, reconsideration of the application and a notice of allowance are respectfully requested.

Summary of the Invention

The present invention, as defined by the claims, as amended herein, is directed to a targeted therapeutic delivery system for the controlled delivery of a therapeutic compound to a region of a patient. The therapeutic delivery system comprises stabilized lipid microspheres in combination with a therapeutic compound. The stabilized microspheres of the therapeutic delivery system are further defined as encapsulating a gas or gaseous precursor and an oil and wherein the oil further encapsulates the gas or gaseous precursor. Also, the lipid of the stabilized lipid microspheres comprises at least one phosphatidylcholine, at least one phosphatidylethanolamine, and at least one phosphatidic acid.

Double Patenting Rejection

Claims 1, 47, 50, 51 and 55 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-102 of U.S. Patent No. 6,146,657, claims 111-173 of U.S. Patent No. 6,139,819, claim 95 of U.S. Patent No. 6,071,494, and claims 57-122 of U.S. Patent No. 6,414,139 (Office Action at 3). In making this rejection, the Office Action states that "selecting an oil to improve the stability of a bioactive agent is well within the level of ordinary skill in the art and further is a function of the bioactive agent employed with the therapeutic system" (Office Action at 3). As explained more fully below with regard to the pending rejections under 35 U.S.C. §§ 102 and 103, the claimed targeted therapeutic delivery system that includes stabilized lipid microspheres encapsulating a gas or gaseous precursor and an oil, wherein said oil further encapsulates said gas or gaseous precursor and wherein said lipid comprises at least one phosphatidylcholine, at least one phosphatidylethanolamine, and at least one phosphatidic acid, would not have been obvious to one of ordinary skill in the art. Accordingly, it is respectfully submitted that the pending double patenting rejection is improper and should be withdrawn.

If the Examiner continues to maintain that the rejection under the judicially created doctrine of obviousness-type double patenting is appropriate, however, Applicant proposes to file a terminal disclaimer as provided in 37 C.F.R. § 1.130(b) once the Examiner has issued a favorable ruling indicating that the amended claims will be allowed. Applicant proposes to file the terminal disclaimer to facilitate prosecution and Applicant expresses no opinion as to whether the obviousness-type double patenting rejection is warranted in view of the cited patents.

Rejection under 35 U.S.C. § 102

Claims 1, 47 and 51 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,498,421 to Grinstaff et al. ("Grinstaff"). The Office Action states that "Grinstaff is the same as the instant targeted delivery systems of claims 1, 47, 51" (Office Action at 4-5). Applicant respectfully disagrees with this rejection, but in the interest of facilitating prosecution, Applicant has incorporated dependent claim 49 into independent claim 1 such that claim 1 now recites, in part, that "said lipid comprises at least one phosphatidylcholine, at least one phosphatidylethanolamine, and at least one phosphatidic

acid" (*see* amended claim 1). Accordingly, Applicant submits that the pending rejection of claims 1, 47 and 51 as being anticipated by Grinstaff is moot, and Applicant respectfully requests that this rejection be withdrawn.

Rejection under 35 U.S.C. § 103

Claims 1, 47, 50, 51, and 55 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,261,537 to Klaveness et al. ("Klaveness").

Applicant respectfully submits that the pending rejection over Klaveness is improper since Klaveness is not prior art against the pending application. The present application is a divisional of U.S. Application Serial No. 09/075,343 filed May 11, 1998, which claims the benefit of U.S. Provisional Application No. 60/046,379, filed May 13, 1997. Accordingly, this application is entitled to a priority date at least as early as May 13, 1997.

Klaveness claims priority to Provisional Application No. 60/049,264 filed June 7, 1997, Provisional Application No. 60/049,265 filed June 7, 1997 and Provisional Application No. 60/049,268 also filed June 7, 1997. Klaveness is also a continuation-in-part of U.S. Application Serial No. 08/958,993, filed Oct. 28, 1997. Klaveness also claims priority to a series of applications filed in Great Britain from October 28, 1996 to June 6, 1997.

As explained in the MPEP, Klaveness is *not* entitled to an effective filing date of one of the British priority applications for prior art purposes against the present application:

> Foreign applications' filing dates that are claimed (via 35 U.S.C. 119(a) – (d), (f) or 365(a)) in applications, which have been published as U.S. or WIPO application publications or patented in the U.S., may not be used as 35 U.S.C. 102(e) dates for prior art purposes. This includes international filing dates claimed as foreign priority dates under 35 U.S.C. 365(a). Therefore, the foreign priority date of the reference under 35 U.S.C. 119(a)-(d) (f), and 365(a) cannot be used to antedate the application filing date

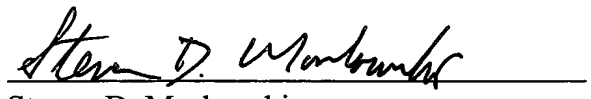
(MPEP § 2136.03).

Because Applicant's provisional filing date of May 13, 1997, antedates any U.S. priority filing in Klaveness (the earliest of which was June 7, 1997), Klaveness is *not* available as prior art against this application. Accordingly, Applicant respectfully submits that the pending rejection under Section 103 is improper and should be withdrawn.

CONCLUSION

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. Accordingly, Applicants respectfully request allowance of all pending claims.

Date: April 20, 2005



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